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HACCP-9

Generic HACCP Model for Meat and Poultry Products with Secondary Inhibitors, Not Shelf Stable

Additional copies of the Guidebook for the Preparation of HACCP Plans and the Generic HACCP Models are available from:

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United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

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TO THE USERS OF THESE VOLUMES

As some of you may know, the Food Safety and Inspection Service (FSIS) received a substantial package of comments on its Guidebook for Hazard Analysis and Critical Control Point (HACCP) Plan Development and the 13 Generic HACCP models, from a coalition of industry and trade associations. This package represents a large and thoughtful effort on the part of these organizations. FSIS intends to give it the careful attention and response that it deserves.

The comments included many technical suggestions for improvements in the FSIS documents. It also included reiteration of longstanding differing policy viewpoints that have been frequently discussed by the Agency and the regulated industry. For the first time, the comments revealed substantially differing expectations on the part of these organizations and FSIS with respect to the purpose of the FSIS documents and their intended use. We want to address some aspects of this latter point.

When the Pathogen Reduction/Hazard Analysis and Critical Control Point systems (PR/HACCP) final regulation was published on July 25, 1996, the DRAFT Guidebook was included as an appendix. The Generic Models, developed for FSIS under contract, were available shortly thereafter in April 1997. It was probably inevitable that there were significant differences between the final regulatory language of CFR Part 417 and the DRAFT Generic Models as they were developed independently. It would have been inappropriate for FSIS to discuss its final regulatory language with any outside group. The contractor was appropriately proceeding from what it knew best, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) documents on the subject of HACCP. Therefore, FSIS accepted that work product with full knowledge that significant revisions would be necessary.

As time passed, FSIS managers became increasingly uncomfortable with the situation in which its major technical assistance documents did not appropriately and completely inform the regulated industry of Agency expectations regarding regulatory compliance. Because the intended audience for these technical assistance materials was primarily the very small establishments, which the Agency believed to have the least HACCP-experience, the Agency began the systematic revision of the documents to overcome this problem. We targeted the summer of 1999 as the completion date for this effort.

FSIS now believes that others had very different ideas about the purpose and use of the documents than it did. As is consistently reiterated in the documents themselves, they are not designed to be used "as is." That is, they cannot be copied and used by an establishment to meet all the regulatory requirements of 9 CFR Part 417. Nor were they designed to be the ultimate teaching and training materials, as some would suggest. The development of ideal generic models is left to others who may have an interest in doing so. The generic models are not

designed to extend or further interpret existing regulations; rather, they are designed to send the user back to the regulations so he/she can become familiar with the requirements as well as the flexibility they permit. The generic models are not designed to present new or alternative methods of producing and processing meat and poultry products. That is also left to others with an interest in doing so.

FSIS envisioned that the generic models might be used in the following way: Suppose a HACCP team leader of a three-person HACCP team in a very small establishment attended a training course, but the others on his/her team were not able to do so. Suppose the HACCP training course met all the requirements of 417.7 but did not provide participants with much in the way of "take away materials" like workbooks, practical questions and answers, access to follow-up resources, etc., which the Research Triangle Institute (RTI) needs assessment indicated were so important to these establishments. The trained HACCP team leader returns to the establishment and begins the process of attempting to develop HACCP plans for the company's products and processes. He/she is quite confident that he/she has grasped the material presented in the training course and begins to work with this team immediately, while the concepts are fresh in his/her mind.

First, he/she has the rest of the team review the Canadian video and the Guidebook from FSIS so that all members of his team have a basic level of information.

The team members begin their work, and as they proceed, some questions arise as to whether what they have developed is appropriate. This is the point when FSIS expects the team to pick up the appropriate generic model and get a sense of whether they are on the right track. They should be able to determine whether the forms that they have developed, while different from the various ones in the generic models and not the same as what other companies use, are acceptable because they include the required information. They will also be able to discover what are some typical food safety hazards that are reasonably likely to occur, as explicitly defined in 417.2, and how to think through the problems that these hazards represent for their own products. They can see how critical limits might arise from existing regulatory requirements like the ones for rapid chilling of poultry products. They can also see that in the absence of settled regulatory requirements, there may be several sources of scientific expertise, and they can choose to make a conservative decision to provide a good margin of safety. They can find out the essential differences between monitoring and verification and have a basis for making their choices about verification activities and their frequencies. FSIS believes that these are useful, beneficial and worthwhile functions for which its generic models can be used.

FSIS is publishing these updated revisions of the generic models, beginning with the Guidebook and the Generic Model for Raw, Ground Product, because a large backlog of requests exists for these two documents. FSIS intends to publish revisions of all the generic models no later than September 30, 1999. Moreover, as a result of public consultation, it may publish an additional revision of some of these models, but given the backlog and the impending HACCP implementation date, we considered it important to get a version of these documents out now.

We hope that these documents are helpful.

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GENERIC HACCP MODEL

FOR

MEAT AND POULTRY PRODUCTS

WITH SECONDARY INHIBITORS, NOT SHELF STABLE

Introduction

The Hazard Analysis Critical Control Point (HACCP) system is a scientific approach to process control. It is designed to prevent the occurrence of problems by assuring that controls are applied at any point in a food production system where hazardous or critical situations could occur. Hazards include biological, chemical, or physical contamination of food products.

The Food Safety and Inspection Service (FSIS) published a final rule in July 1996 mandating that HACCP be implemented as the system of process control in all inspected meat and poultry plants. As part of its efforts to assist establishments in the preparation of plant-specific HACCP plans, FSIS determined that a generic model for each process defined in the regulation would be made available for use on a voluntary basis by inspected establishments.

The generic models have been revised since their initial publication and distribution as DRAFTS. The most important change in the revised versions is to make certain that these models are fully consistent with the features of the final regulation. Also, other technical and editorial improvements have been made.

Throughout this generic model, FSIS discusses a HACCP team with members from different departments. In many very small establishments, there will not be separate departments with different employees. But, there will be employees who perform these different functions – often several of them. For purposes of explaining concepts, it is easier to speak as if these were different people, even though in many cases, they may be the same person carrying out more than one responsibility.

Each generic model can be used as a starting point for the development of plant-specific plan(s) reflecting actual plant environments and the processes conducted. The generic model is not intended to be used "as is" for plant specific HACCP plans.

The generic models are designed for use in conjunction with the list of process categories found in the HACCP regulations in section 417.2(b)(1).

> *(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:*
>
> *(i) Slaughter--all species.*
>
> *(ii) Raw product--ground.*
>
> *(iii) Raw product--not ground.*
>
> *(iv) Thermally processed--commercially sterile.*

(v) Not heat treated--shelf stable.

(vi) Heat treated--shelf stable.

(vii) Fully cooked--not shelf stable.

(viii) Heat treated but not fully cooked--not shelf stable.

(ix) Product with secondary inhibitors--not shelf stable.

This generic model is designed for use with the process category: Product with secondary inhibitors--not shelf stable.

The purpose of the process category listing in 417.2 is to set out the circumstances under which a HACCP team may develop a single HACCP plan for multiple products. This may be done when products are in the same process category, and food safety hazards, critical control points, and other features are essentially the same. There is a generic model for each process category, plus two for subcategories which present special issues: irradiated products and mechanically separated products.

In order to select the model or models that will be most useful for the activities performed in any specific plant, the following steps should be taken:

1) For slaughtering operations, select the model for the appropriate species.

2) For processed products, make a list of all products produced in the plant.

3) Examine the list and group like products, considering common processing steps and equipment used.

4) Compare the grouped products with the list of processes in the regulations; this step should reveal how many and which of the generic models might be useful.

Deciding on a generic model and which products can be covered by a single plan is an important achievement. If the team does it well, it can save a lot of unnecessary effort and paperwork.

Selecting an inappropriate generic model reduces its potential benefits. However, often the HACCP team will discover they have made this error when they develop their process flow diagram or during their hazard analysis. These are early stages in the process when it is relatively easy to make changes.

In any case, establishments must meet all regulatory requirements for their products.

Using This Generic Model

This generic model is designed to be used by establishments that produce product(s) with secondary inhibitors, not shelf stable, the ninth process category. The model can be used for all products with secondary inhibitors, not shelf stable: either meat or poultry. The generic model is not suitable for products that fall into any of the other process categories.

The model will be most useful to a HACCP team that includes access to one trained individual, as specified in 417.7(b).

> *(b)The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.*

It would be beneficial for other team members to have reviewed any of the various guidance materials available on how to develop a HACCP plan for your company, including several useful videos, handbooks, or computer programs. Once the HACCP team has prepared itself as thoroughly as possible in general HACCP principles and how to use them, this model should be helpful.

Note: This generic model includes a number of forms that can be used to record various types of required information. The forms themselves are samples; a company HACCP team can develop whatever forms it finds most useful. All the forms mentioned in this document are included in Appendix B; they appear in the order in which they are discussed in the text.

All FSIS generic models are designed to assist establishments in applying the seven HACCP principles to their meat and poultry processing operations **AND** to meet the regulatory requirements of Part 417. Therefore, the definitions used in this and all other FSIS generic models are those found in 417.1:

> ***§ 417.1 Definitions.***
>
> *For purposes of this part, the following shall apply:*
>
> *Corrective action. Procedures to be followed when a deviation occurs.*
>
> *Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.*
>
> *Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.*
>
> *Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.*
>
> *HACCP System. The HACCP plan in operation, including the HACCP plan itself.*
>
> *Hazard. SEE Food Safety Hazard.*
>
> *Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.*
>
> *Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.*
>
> *Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.*

Process Flow Diagram and Product Description

To begin using this model, the company's HACCP team should first describe the product(s) which are part of this process category and covered by this HACCP plan. The product(s) should be described in two ways:

(1) by a simple diagram which shows the steps the company uses when it produces the product, and
(2) in a brief written description which provides key facts about the product and its use.

In this generic model, there is an example for products with secondary inhibitors, not shelf stable – corned (cured) beef. FSIS has developed certain forms as part of the examples in the generic models; **company HACCP teams are not required to use these forms.**

Figure 1 is an example of a **PROCESS FLOW DIAGRAM** for the production of corned beef in generic establishment X. Figure 2 is an example of a **PRODUCT DESCRIPTION** for the corned beef produced in generic establishment X.

Once the company HACCP team in your establishment has prepared your Process Flow Diagram, they should verify it by walking through the establishment following the flow of product and making sure that all the steps of the process are included in the flow diagram. The team should also review the information provided on the Product Description to make sure all the key facts are included, such as identifying consumers, especially those with particular health problems or known to be at risk.

Note: If your process includes steps not included in this example, those steps should be added. Also, if your process does not include all the steps identified in this example, those steps would be omitted when conducting the hazard analysis. That is generally, how you use these generic model examples--just omit the features which do not apply to your operation or if your operation includes features not included in this example, they should be added.

By completing a Process Flow Diagram and a Product Description, you have met the requirements of 417.2(a)(2). You can use the Process Flow Diagram in particular to help you complete the rest of the hazard analysis. Use the flow diagram to systematically review each step in the process and ask the question, "Is there a food safety hazard which is reasonably likely to occur which may be introduced at this step?" In answering the question, your HACCP team needs to consider biological (including microbiological), chemical, and physical hazards.

Hazard Analysis

Once your product(s) are accurately described through the flow diagram and product description, the HACCP team should begin work on the **HAZARD ANALYSIS**. The hazard analysis is fundamental to developing a good HACCP plan and one that meets regulatory requirements. The regulatory requirements for a hazard analysis are found at 417.2(a).

> ***§ 417.2 Hazard Analysis and HACCP Plan.***
>
> *(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.*
>
> *(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.*

Generic establishment X, which we are using for our example, is capturing these regulatory requirements on a 6-column **Hazard Analysis Form (See Figure 3)**. A good way to use a form like this is to create the first column by using the Process Flow Diagram and the second by answering the question. Once the HACCP team has considered all the steps in the flow diagram and determined if a food safety hazard could be introduced, it needs to consider whether the hazard is "reasonably likely to occur", using the meaning of this phrase included in 417.2(a). On the 6-column form used by generic establishment X, the third and fourth columns address this issue. If the establishment's HACCP team has decided that the hazard is not reasonably likely to occur, they enter "No" in column three, explain the basis for their determination in column four, and do not need to further consider activity at this point in the process.

If, however, the team has determined there is a "food safety hazard reasonably likely to occur" introduced at a certain point in the process, column five is used to describe a measure which could be applied to "prevent, eliminate, or reduce to acceptable levels" the food safety hazard identified in column three. Column six is used when a critical control point (CCP) is identified based upon the decision made in the hazard analysis. Each CCP has a number – the order corresponds to steps in the process. For example, 1 is the first CCP in the process flow, 2 the next, etc. The letter indicates whether the hazard is biological – B; chemical – C; or physical – P.

Look at the entries for “Receiving” on the first page of the six column form for products with secondary inhibitors, not shelf stable; the HACCP team has determined that *Salmonella* and *E. coli* O157: H7 may be food safety hazards, so it has put a “Yes” in the third column. Column four explains the basis for the team’s determination. In the fifth column, the HACCP team has described the preventive measures it will use to make sure that each hazard has been prevented, eliminated, or reduced to an acceptable level. For this hazard, the HACCP team decided that the plant will require certification from suppliers that *Salmonella* performance standards have been met. FSIS does not consider safe handling labels alone to be an adequate CCP for any pathogenic microorganisms such as bacteria and viruses.

Note: Look at the entries for “Storage – (Cold – Frozen/Refrigerated) – Raw Beef” on the second page of the six-column form: the HACCP team has determined that there is a food safety hazard reasonably likely to occur at this step in the process. Column four contains the reason for their thinking: pathogenic organisms can grow in this

product if it is not kept sufficiently cool. Column five contains their description of a measure that will prevent the growth of pathogenic organisms: temperatures that are sufficiently low to preclude growth.

You will notice that on our generic hazard analysis for corned beef, there are five food safety hazards in which the HACCP team has identified a point in the process at which a food safety hazard is reasonably likely to occur. For each one of these they have identified a measure which can be used to control the hazard.

When your HACCP team has completed their hazard analysis (whether they use this format or not), it is a good idea to review the flow diagram, the product description and the hazard analysis itself to make sure they are complete. Part 417.2(a)(3) includes a list of sources from which food safety hazards might be expected to arise. Reviewing that list could help the HACCP team check for completeness.

Note: If you are using this generic model to produce a different product with secondary inhibitors, not shelf stable or if you use a different process flow, you may have different hazards which are reasonably likely to occur. For these different hazards, there may be different measures which could be used for control purposes.

This, and all other FSIS generic models, contains a list of references which can help your HACCP team in making sure the hazard analysis is complete. These references are found in Appendix A. A member of your HACCP team might want to review at least some of the references to make sure hazards have not been omitted from the hazard analysis.

Completing the hazard analysis is a very significant and important element in developing your HACCP system. Your HACCP team should feel a real sense of accomplishment when they get this far; this is like completing the foundation of a house.

Developing Your HACCP Plan

The company HACCP team can now take the materials it developed while doing the hazard analysis and use them to build the **HACCP Plan.** Remember that one of the important objectives of the FSIS generic models is to provide examples which illustrate **how to meet the regulatory requirements of Part 417**, as well as to correctly apply the principles of HACCP. Part 417.2 (c) and (d) are the regulatory requirements:

> *(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:*
>
> *(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.*
>
> *(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:*
>
> *(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and*
>
> *(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;*
>
> *(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;*
>
> *(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;*

(5) Include all corrective actions that have been developed in accordance with §417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

Generic establishment X has prepared its HACCP plan for corned beef on a six column form (**See Figure 4**). You do not need to use this form, although some kind of a form is probably the easiest way to present your HACCP plan.

Identifying CCPs

The first column on this particular form is used to enter information developed and contained on the hazard analysis form. Part 417.2(c)(1) and (2) require that the food safety hazards identified in the hazard analysis be listed on the HACCP plan and that there be a CCP for each identified hazard. You will notice that there were five points on the hazard analysis form for corned beef where food safety hazards reasonably likely to occur were identified: *Salmonella* on raw beef at receiving, pathogen proliferation at cold storage, excess nitrite in finished product, pathogen survival and/or proliferation at curing, and pathogen contamination at finished product storage. The establishment HACCP team has chosen to have five CCPs to address these five hazards: *Salmonella* certification, proper cold storage of raw beef, proper control and formulation of nitrite, proper curing application, and proper finished product cold storage.

After identifying its CCPs, the HACCP team proceeded to consider critical limits, monitoring procedures and their frequencies, and verification procedures and their frequencies, and HACCP records.

In deciding what would be the critical limits, the HACCP team first considered whether there were any regulatory requirements which had to be met and would function as critical limits.
They did find FSIS regulatory requirements and guidelines, so they set the critical limit(s) using criteria as specified by FSIS for the control of pathogens.

Once they had decided on their critical limits, they needed to identify how the monitoring procedures would be carried out and at what frequency.

For their cure application step, the establishment had Quality Assurance monitor the application of and record the amount of cure and application method.

These decisions by the HACCP team regarding critical limits, plus monitoring procedures and their frequencies are written up in columns two and three of the HACCP Plan.

The team then went on to consider appropriate verification procedures; the team knew that there were different types of verification and that Part 417.4(a)(2) included specific regulatory requirements for each. The regulatory requirements for ongoing verification are:

> *(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:*
>
> *(i) The calibration of process-monitoring instruments;*
>
> *(ii) Direct observations of monitoring activities and corrective actions; and*
>
> *(iii) The review of records generated and maintained in accordance with §417.5(a)(3) of this part.*

The HACCP team decided they could verify through the following procedures and frequency:

The HACCP team described the verification procedures and their frequencies in the fifth column of their HACCP plan.

The HACCP team for generic establishment X knew that their HACCP Plan needed to provide for a recordkeeping system. They wanted their records to be easy to create and understand. They wanted to be sure their records met regulatory requirements, so they reviewed part 417.5(a) and (b):

> ***§ 417.5 Records.***
>
> *(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:*
>
> *(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;*
>
> *(2) The written HACCP plan, including decision making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.*
>
> *(3) Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.*
>
> *(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.*

The HACCP team decided that their records would be kept on some simple forms, some of which the team itself devised.

The HACCP team decided that five forms were necessary: Form letter for *Salmonella*, Thermometer Calibration Log, Room Temperature Log, Pump Percentage Log, and Weight Formulation Record. The forms were designed to provide spaces for all entries necessary for the monitoring and verification activities at each CCP.

On its HACCP Plan, generic establishment X has listed the name of the form it will be using for monitoring and verification records.

There is one other form included in column four, where the establishment has described its recordkeeping system. That is the Corrective Actions Log; it is used to create the records of any corrective actions taken because of deviations from critical limits at CCPs. Column six of the HACCP plan references the planned corrective actions for each CCP. The HACCP team carefully reviewed the regulatory requirements for planned corrective actions found at 417.3(a):

> ***§ 417.3 Corrective actions.***
>
> *(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:*
>
> *(1) The cause of the deviation is identified and eliminated;*
>
> *(2) The CCP will be under control after the corrective action is taken;*
>
> *(3) Measures to prevent recurrence are established; and*
>
> *(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.*

The HACCP team has developed a specific corrective action plan which will be followed whenever there is a deviation from a critical limit at a CCP; each of the planned corrective actions meets the four regulatory requirements of 417.3(a).

Planned Corrective Actions for CCP 3C:

1. Improperly prepared cure ingredients will be discarded.

2. QA will identify the cause of the deviation and prevent reoccurrence.

3. Monitoring will be increased to include scale calibration for each batch.

The HACCP team also develops planned corrective actions for each of the other CCPs and attaches them to the HACCP plan. Whenever a deviation from a critical limit occurs, company employees follow the corrective action plan and use the Corrective Action Log to create a record of their actions. The Corrective Action Log forms are available at CCPs, so they can be used immediately when an employee performing a monitoring check discovers and records a deviation. All Corrective Action Logs, which have been used during the day, are turned in to the HACCP coordinator.

There is one final verification/recordkeeping requirement which the company must perform; it is found at 417.5(c):

> *(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.*

In generic establishment X, product is shipped out, often in small lots, throughout the day. This means that pre-shipment verification checks must be as complete as possible when finished product is in storage, so that a shipment can be made up quickly and moved into distribution channels.

The establishment uses a half day lotting system and a midshift cleanup. While the midshift cleanup is being performed, QA personnel or the HACCP coordinator review results of monitoring and verification checks applied to that lot; if there were deviations from critical limits, they review the Corrective Action Logs to make sure all appropriate planned responses were carried out. If everything is in order and there are complete records showing

that the establishment has controlled production of this product through its HACCP system, the HACCP coordinator will sign the pre-shipment review form which the HACCP team devised for this purpose.

Note: It is not a regulatory requirement that a separate form be used for pre-shipment review; in addition, FSIS has indicated that it will be very flexible in accepting a variety of arrangements for accomplishing pre-shipment review to reflect the variety of commercial practices which it has encountered in the industry. It is, however, important to remember that pre-shipment review is a regulatory requirement that must be met, as it indicates that the establishment is taking full responsibility for the product having been produced under a well-functioning HACCP system.

The HACCP team believes it has now completed preparation of the documents which are necessary to meet regulatory requirements for a Hazard Analysis and a HACCP Plan for their products with secondary inhibitors, not shelf stable production process. They have secured a copy of FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to HACCP System Requirements, the HACCP Basic Compliance Checklist which will be used by inspection program personnel. The HACCP team has modified the inspection form to make the statements into positives, and now has a checklist for its own use to make sure they have not omitted anything in their plan development and preparation. When they are confident that they have done what is necessary, they will turn their Hazard Analysis and HACCP Plan over to the establishment owner for decisions about implementation.

APPENDIX A

References for HACCP Teams

1. Agriculture Canada. *Food Safety Enhancement Program – HACCP Implementation Manual*. Camelot Drive, Nepean, Ontario, Canada, 1996.

2. American Meat Institute Foundation. *HACCP: The Hazard Analysis and Critical Control Point System in the Meat and Poultry Industry.* Washington, D.C., 1994.

   Useful sections in particular are:
   Chapter 3 – microbiological hazards, pp. 15-26
   Chapter 4 – chemical hazards, pp. 27-32
   Chapter 5 – physical hazards, pp. 33-35
   Appendix A – NACMCF HACCP
   Appendix C – Model HACCP plans

3. Baker, D.A. *Application of Modeling in HACCP Plan Development.* Int. J. Food Microbiol. 25:251-261, 1995.

4. Corlett, D.A., Jr. and Stier, R.F. *Risk Assessment within the HACCP System.* Food Control 2:71-72, 1991.

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6. Easter, M.C., *et al*. *The Role of HACCP in the Management of Food Safety and Quality.* J. Soc. Dairy Technol. 47:42-43, 1994.

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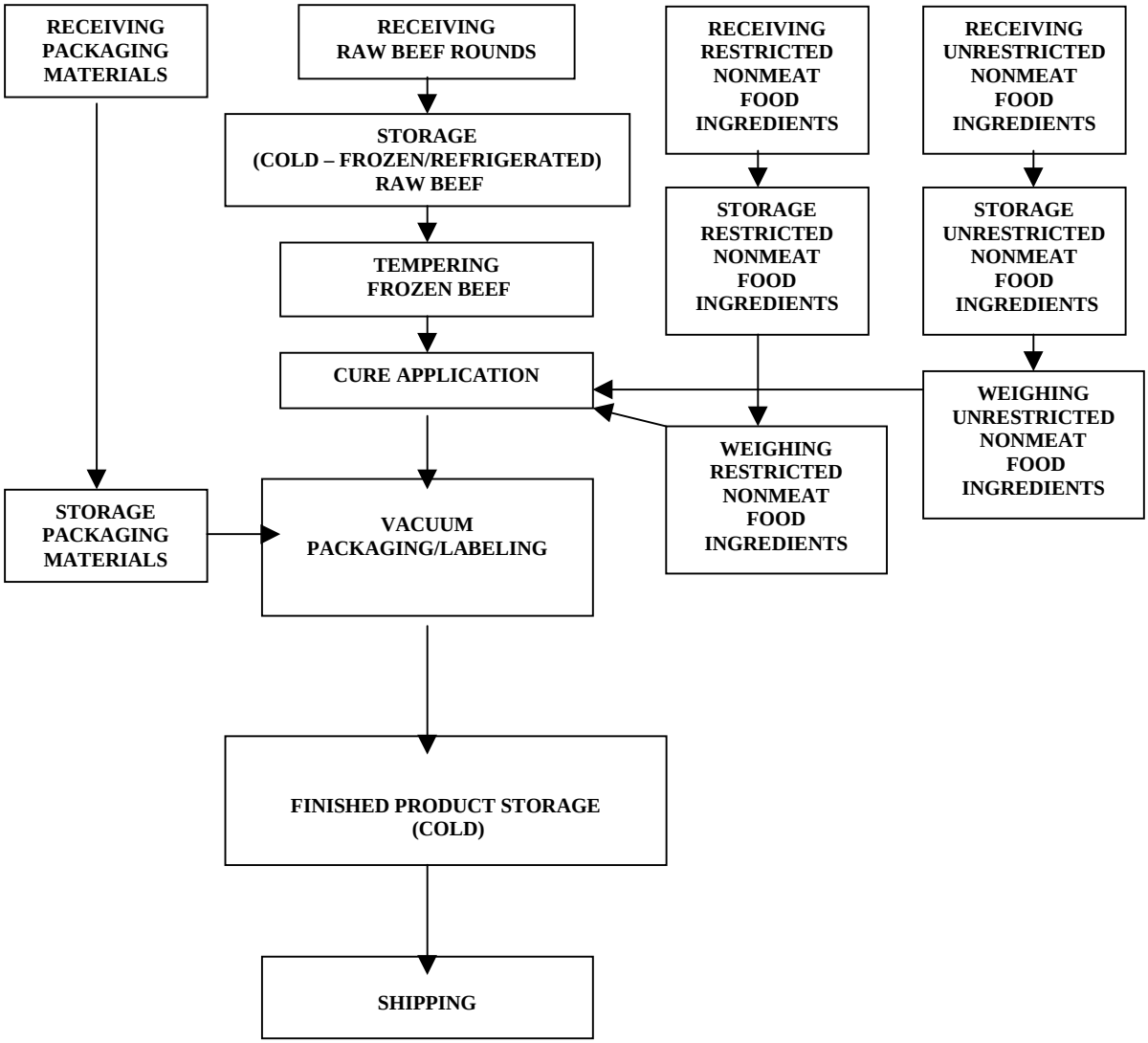
APPENDIX B

PROCESS FLOW DIAGRAM **Figure 1**

PROCESS CATEGORY: PRODUCTS WITH SECONDARY INHIBITORS, NOT SHELF STABLE

PRODUCT: CORNED BEEF



PRODUCT DESCRIPTION

Figure 2

PROCESS CATEGORY: PRODUCTS WITH SECONDARY INHIBITORS, SHELF STABLE PRODUCT: CORNED (CURED) BEEF	
1. COMMON NAME?	CORNED BEEF
2. HOW IS IT TO BE USED?	COOKED BY PURCHASER
3. TYPE OF PACKAGE?	VACUUM PACKED
4. LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE? PRODUCT IS 8 DAYS	UNDER REFRIGERATION SHELF LIFE OF VACUUM PACKAGED FROZEN 14 DAYS
5. WHERE WILL IT BE SOLD? CONSUMERS? INTENDED USE?	WHOLESALE TO DISTRIBUTORS ONLY
6. LABELING INSTRUCTIONS?	KEEP REFRIGERATED OR FROZEN
7. IS SPECIAL DISTRIBUTION CONTROL NEEDED?	KEEP REFRIGERATED OR FROZEN

HAZARD ANALYSIS – PRODUCTS WITH SECONDARY INHIBITORS, NOT SHELF STABLE – Corned Beef

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Receiving – Raw Beef Rounds	**Biological: Pathogens** *Salmonella* *E. coli* O157:H7	**Yes**	***Salmonella* and** *E. coli* O157:H7 **may be present on incoming raw product. Curing process will inhibit growth of pathogens (*E.coli*) at a further step in the process. Proper storage and handling at subsequent steps can reduce the growth of** *E. coli* **if present.**	**Certification from suppliers that product has been sampled for** *Salmonella* **and meets FSIS performance standards.**	**1B**
	Chemical – None				
	Physical – Foreign materials such as broken needles	**No**	**Plant records show that there has been no incidence of foreign materials in products received into the plant.**		

Figure 3

HAZARD ANALYSIS – PRODUCTS WITH SECONDARY INHIBITORS, NOT SHELF STABLE – Corned Beef

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Receiving – Restricted and Unrestricted Nonmeat Food Ingredients; Packaging Materials	**Biological – None**				
	Chemical – Not acceptable for intended use	**No**	**Letters of guaranty are received from all suppliers of packaging materials.**		
	Physical – Foreign materials (insects, glass, metal, etc.)	**No**	**Plant records demonstrate that foreign material contamination has not occurred during the past several years.**		
Storage – Restricted and Unrestricted Nonmeat Food Ingredients; Packaging Materials	**Biological – None**				
	Chemical – None				
	Physical – None				
Storage (Cold – Frozen/Refrigerated) – Raw Beef	**Biological** *E. coli* O157:H7	**Yes**	**Pathogens are reasonably likely to grow in this product if temperature is not maintained at or below a level sufficient to preclude their growth.**	**Maintain product temperature at or below a level sufficient to preclude pathogen growth.**	**2B**
	Chemical – None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – PRODUCTS WITH SECONDARY INHIBITORS, NOT SHELF STABLE – Corned Beef

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Tempering Frozen Beef	**Biological – None**				
	Chemical – None				
	Physical – None				
Weighing Restricted and Unrestricted Nonmeat Food Ingredients	**Biological – None**				
	Chemical – Cure Ingredients (nitrite)	**Yes**	**Excess nitrite in a finished product may create a health hazard.**	**Proper control and formulation of nitrite to prevent creating a health hazard.**	**3C**
	Physical – None				
Cure Application	**Biological** *Clostridium botulinum Clostridium perfringens*	**Yes**	**Application of cure at the proper level will inhibit the growth of pathogenic organisms.**	**Proper injection of cure solution to provide microbial inhibition.**	**4B**
	Chemical – None				
	Physical – None				
Packaging/Labeling	**Biological** *Clostridium botulinum Clostridium perfringens*	**No**	**Proper nitrite pump and vacuum package will allow competing organisms to grow to the exclusion of** *clostridia*.	**See CCP 3C and CCP 4B**	
	Chemical – None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – PRODUCTS WITH SECONDARY INHIBITORS, NOT SHELF STABLE – Corned Beef

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Finished Product Storage (Cold)	**Biological** *Salmonella*	**Yes**	**Pathogens are reasonably likely to grow on this product if temperature is not maintained at or below a level sufficient to preclude their growth.**	**Maintain product temperature at or below a level sufficient to preclude pathogen growth.**	**5B**
	Chemical – None				
	Physical – None				
Shipping	**Biological - None**				
	Chemical – None				
	Physical – None				

Figure 3

HACCP PLAN

PROCESS CATEGORY: PRODUCTS WITH SECONDARY INHIBITORS, NOT SHELF STABLE
PRODUCT EXAMPLE: CORNED BEEF

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
1B Receiving – Raw Beef Rounds	Supplier certification that product has been sampled for *Salmonella* must accompany shipment.	Receiving personnel will check each shipment for *Salmonella* certification.	Receiving Log Corrective Action Log	Every two months QA will request FSIS *Salmonella* data results from the company for at least 2 suppliers.	Will not receive product unaccompanied by *Salmonella* certification.
2B Storage (Cold– Frozen/ Refrigerated – Raw Beef	Raw product storage areas will not exceed 40° F in refrigerated rooms or exceed 28° F in freezer rooms.	Maintenance personnel will check raw product storage area temperature every two hours.	Room Temperature Log Thermometer Calibration Log Corrective Action Log	Maintenance supervisor will verify accuracy of the Room Temperature Log once per shift. QA will check all thermometers used for monitoring and verification for accuracy daily and calibrate to within 2° F accuracy as necessary.	QA will reject or hold product dependent on time and temperature deviation and use pathogen modeling to determine product disposition. QA will identify the cause of the deviation and prevent reoccurrence. Monitoring frequency will be increased until it is assured that the process step is under control.

Signature: _____ Date: _____

Figure 4

HACCP PLAN

PROCESS CATEGORY: PRODUCTS WITH SECONDARY INHIBITORS, NOT SHELF STABLE
PRODUCT EXAMPLE: CORNED BEEF

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
3C Weighing Restricted and Unrestricted Nonmeat Food Ingredients	2 lb. sodium nitrite to 100 gallon pickle at 10% pump.	QA technician will monitor weighing and formulation of sodium nitrite for each batch.	Weight/ Formulation Record Corrective Action Log	QA supervisor will observe QA technician perform monitoring activity once per shift. QA supervisor will check Weight/Formulation Record twice per shift. Scale will be calibrated once per week.	Improperly prepared cure ingredients will be discarded. QA will identify the cause of the deviation and prevent reoccurrence. Monitoring will be increased to include scale calibration for each batch.

Signature: _____ Date: _____

Figure 4

HACCP PLAN

PROCESS CATEGORY: PRODUCTS WITH SECONDARY INHIBITORS, NOT SHELF STABLE
PRODUCT EXAMPLE: CORNED BEEF

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
4B Cure Application	120 ppm sodium nitrite at 10% pump.	Pump percentage will be monitored before and after pump to assure 10% gain. Ten pieces will be weighed before and after pump % gain calculated every 2 hours.	Pump Percentage Log Corrective Action Log	QA will observe pump technician perform pump check once per lot. QA will review pump log once per shift.	Product not meeting critical limit will be held and either repumped to 10% or drained to 10%. Needle settings will be checked and adjusted as required. Pump technician will monitor every hour until assured that the CCP is under control.

Signature: _____ Date: _____

Figure 4

HACCP PLAN

PROCESS CATEGORY: PRODUCTS WITH SECONDARY INHIBITORS, NOT SHELF STABLE
PRODUCT EXAMPLE: CORNED BEEF

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
5B Finished Product Storage	Product storage area will not exceed 40°F	Maintenance personnel will monitor storage room temperature once per shift.	Corrective Action Log Room Temperature Log Thermometer Calibration Log	QA will observe maintenance personnel perform storage temperature monitoring and review room temperature log once per week. Cooler thermometers will be calibrated once per week by maintenance supervisor.	If room temperature exceeds 40° F product will be held and internal temperature taken. Internal product temperature and amount of time product and room temperature deviated will determine product disposition. Product temperature will be monitored when room temperature is monitored until CCP is under control. Cause of deviation will be identified. Maintenance will repair thermometer units or cooling coils as required based on cause of deviation.

Signature: _____ Date: _____

Figure 4

FORM LETTER Confirming *Salmonella* Compliance with Performance Standards

Date

To: Plant XYZ

This is to confirm results of any *Salmonella* performance standard sample sets completed during the past six months from your establishment listed below.

Thank you.

Product	Date Results Received	Test Results	Two Consecutive Failed Tests

THERMOMETER CALIBRATION LOG

Calibrate to 32^0 F while thermometer is in slush ice water

Date	Time	Department or Area	Thermometer ID#	Personal Thermometer Reading	Adjustment Required (Yes or No)	Initials	Comments

- **If a thermometer is broken or taken out of service, document this in the comment column**.

Reviewed by: _____ Date: _____

WEIGHT / FORMULATION RECORD							
Date	Time	Lot #	Weight Sodium Nitrite	No. of Gallon Pickle	PPM	Initials	Comments

Reviewed by: _____ Date: _____

PUMP PERCENTAGE LOG							
Date	Time	Lot #	Weight Before Pump	Weight After Pump	% Gain	Initials	Comments

Reviewed by: _____ Date: _____

GENERIC ESTABLISHMENT X: ROOM TEMPERATURE LOG

ROOM:_____ **DATE**:_____

TIME	TEMP	Deviation from CL? (Check if yes)	If Yes, Action?	Monitored by:	Verified by:

CORRECTIVE ACTIONS LOG

Product: _____ **Lot # _____**

CCP	Deviation/ Problem	Corrective Action Procedures/Explain	Disposition of Product	Responsible Person	Date/Time

SIGNATURE: _____ **DATE: _____**

PRE-SHIPMENT REVIEW LOG

Date:_____

PRODUCT	LOT ID	TIME RECORDS REVIEWED	BY WHOM	LOT RELEASED FOR SHIPMENT? SIGNATURE	COMMENTS *

*Monitoring frequency as per plan; Critical limits met; Certification (if applicable) as per plan; Deviations if occurred were reviewed for appropriate corrective actions; Records complete and accurate.